

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A nucleic acid-cationic immunoliposome complex comprising i) a cationic liposome, ii) an antibody or antibody fragment, and iii) a nucleic acid wherein said nucleic acid-cationic immunoliposome complex is prepared by a method comprising the steps of:
    - ~~1) a) mixing said nucleic acid with said cationic liposome to produce a nucleic acid-liposome complex;~~
    - ~~b) preparing said antibody or antibody fragment; and~~
    - ~~c) mixing said nucleic acid-liposome complex with said antibody or antibody fragment to form said nucleic acid-cationic immunoliposome complex; or~~
  - 2) a) preparing said antibody or antibody fragment;
    - b) mixing said antibody or antibody fragment with said cationic liposome to form a cationic immunoliposome; and
    - c) mixing said cationic immunoliposome with said nucleic acid to form said nucleic acid-cationic immunoliposome complex;
- wherein said antibody or antibody fragment and said cationic liposome are present at a protein:lipid ratio (w:w) in the range of 1:5 to 1:40 and wherein said

nucleic acid and said cationic liposome are present at a nucleic acid:lipid  
( $\mu\text{g}:\text{nmol}$ ) ratio in the range of 1:6 to 1:20.

2. (Original) The nucleic acid-cationic immunoliposome complex of claim 1 wherein said antibody or antibody fragment is capable of binding to a transferrin receptor.
3. (Original) The nucleic acid-cationic immunoliposome complex of claim 1 wherein said nucleic acid is DNA.
4. (Original) The nucleic acid-cationic immunoliposome complex of claim 1 wherein said nucleic acid encodes a wild type p53.
5. (Original) The nucleic acid-cationic immunoliposome complex of claim 1 wherein said antibody or antibody fragment comprises a lipid tag.
6. (Original) The nucleic acid-cationic immunoliposome complex of claim 1 wherein said antibody or antibody fragment is covalently bound to said cationic liposome via a sulfur atom which was part of a sulfhydryl group at a carboxy terminus on said antibody or antibody fragment.

7. (Original) The nucleic acid-cationic immunoliposome complex of claim 6 wherein said sulfur atom is part of a cysteine residue.
8. (Original) The nucleic acid-cationic immunoliposome complex of claim 6 wherein said antibody or antibody fragment is covalently bound to DOPE linked to MPB or other sulfhydryl reacting group.
9. (Original) The nucleic acid-cationic immunoliposome complex of claim 1 wherein said antibody fragment is a single chain.
- 10-11. (Canceled)
12. (Original) A pharmaceutical composition comprising the nucleic acid-cationic immunoliposome complex of claim 1.
- 13-25. (Canceled)
26. (Currently amended) A method of preparing a nucleic acid-cationic immunoliposome complex comprising the steps of:
  - a) preparing an antibody or antibody fragment;

b) mixing said antibody or antibody fragment with a cationic liposome to form a cationic immunoliposome; and

c) mixing said cationic immunoliposome with nucleic acid to form said nucleic acid-cationic immunoliposome complex;

wherein said antibody or antibody fragment and said cationic liposome are present at a protein:lipid ratio (w:w) in the range of 1:5 to 1:40 and wherein said nucleic acid and said cationic liposome are present at a nucleic acid:lipid ( $\mu\text{g}:\text{nmol}$ ) ratio in the range of 1:6 to 1:20.

27. (Original) The method of claim 26 wherein said nucleic acid encodes a wild type p53.
28. (Original) The method of claim 26 wherein said antibody or antibody fragment is capable of binding to a transferrin receptor.
29. (Original) The method of claim 26 wherein said antibody or antibody fragment comprises a lipid tag.
30. (Original) The method of claim 26 wherein said antibody or antibody fragment comprises a reducible group at a carboxy terminus prior to mixing with said nucleic acid-liposome complex.

31. (Original) The method of claim 30 wherein said reducible group is a sulfhydryl.
32. (Original) The method of claim 31 wherein said sulfhydryl is part of a cysteine residue.
33. (Original) The method of claim 31 wherein said antibody or antibody fragment is covalently bound to said cationic liposome via a sulfur atom of said reducible group.
34. (Original) The method of claim 30 wherein said cationic liposome comprises MPB-DOPE.
35. (Original) The method of claim 26 wherein said nucleic acid is DNA.
- 36-37. (Canceled)
38. (Original) The method of claim 26 wherein said antibody fragment is a single chain.
39. (Currently amended) A method for providing a therapeutic molecule to an animal in need thereof, comprising administering to said animal a therapeutically

effective amount of a nucleic acid-cationic immunoliposome complex comprising  
i) a cationic liposome, ii) an antibody or antibody fragment, and iii) a nucleic acid  
wherein said nucleic acid-cationic immunoliposome complex is prepared by a  
method comprising the steps of:

~~1) a) mixing said nucleic acid with said cationic liposome to produce a  
nucleic acid-liposome complex;~~

~~b) preparing said antibody or antibody fragment; and~~

~~c) mixing said nucleic acid-liposome complex with said antibody or  
antibody fragment to form said nucleic acid-cationic immunoliposome  
complex; or~~

2) a) preparing said antibody or antibody fragment;

b) mixing said antibody or antibody fragment with a cationic liposome to  
form a cationic immunoliposome; and

c) mixing said cationic immunoliposome with said nucleic acid to form said  
nucleic acid-cationic immunoliposome complex;

wherein said antibody or antibody fragment and said cationic liposome are  
present at a protein:lipid ratio (w:w) in the range of 1:5 to 1:40 and wherein said  
nucleic acid and said cationic liposome are present at a nucleic acid:lipid  
( $\mu$ g:nmol) ratio in the range of 1:6 to 1:20.

40. (Original) The method of claim 39 wherein said complex is administered systemically.
41. (Original) The method of claim 39 wherein said complex is administered intravenously.
42. (Original) The method of claim 39 wherein said antibody or antibody fragment is capable of binding to a transferrin receptor.
43. (Original) The method of claim 39 wherein said antibody fragment is a single chain.
44. (Original) The method of claim 39 wherein said nucleic acid is DNA.
45. (Original) The method of claim 39 wherein said nucleic acid encodes a wild type p53.
46. (Original) The method of claim 39 wherein said antibody or antibody fragment comprises a lipid tag.

47. (Original) The method of claim 39 wherein said antibody or antibody fragment is covalently bound to said cationic liposome via a sulfur atom which was part of a reducible group at a carboxy terminus on said antibody or antibody fragment.
48. (Original) The method of claim 47 wherein said reducible group is a sulfhydryl.
49. (Original) The method of claim 48 wherein said sulfhydryl is part of a cysteine residue.
50. (Original) The method of claim 47 wherein said antibody or antibody fragment is covalently bound to DOPE linked to MPB or other sulfhydryl reacting group.
- 51-52. (Canceled)
53. (Original) The method according to claim 39 wherein said animal is a human.
54. (Original) The method according to claim 39 wherein said animal has cancer.
55. (Original) The method according to claim 54 wherein said cancer is selected from the group consisting of i) head and neck cancer, ii) breast cancer and iii) prostate cancer.



56. (Currently amended) A kit comprising

- i) a nucleic acid;
- ii) a cationic immunoliposome; and
- iii) an instruction manual for preparing a nucleic acid-cationic immunoliposome complex prepared by a method comprising the steps of:

~~1) a) mixing said nucleic acid with said cationic liposome to produce a nucleic acid-liposome complex;~~

~~\_\_\_\_\_ b) preparing an antibody or antibody fragment; and~~

~~\_\_\_\_\_ c) mixing said nucleic acid-liposome complex with said antibody or antibody fragment to form said nucleic acid-cationic immunoliposome complex; or~~

2) a) preparing an antibody or antibody fragment;

b) mixing said antibody or antibody fragment with said cationic liposome to form a cationic immunoliposome; and

c) mixing said cationic immunoliposome with said nucleic acid to form said nucleic acid-cationic immunoliposome complex;

wherein said antibody or antibody fragment and said cationic liposome are

present at a protein:lipid ratio (w:w) in the range of 1:5 to 1:40 and wherein said

nucleic acid and said cationic liposome are present at a nucleic acid:lipid

( $\mu$ g:nmol) ratio in the range of 1:6 to 1:20.

- 57. (Original) The kit of claim 56 wherein said nucleic acid encodes a wild type p53.
- 58. (Original) The kit of claim 56 wherein said cationic liposome comprises an antibody or antibody fragment capable of binding to a transferrin receptor.
- 59. (Original) The kit of claim 56 wherein said antibody fragment is a single chain.
- 60. (Original) The kit of claim 56 wherein said antibody fragment comprises a lipid tag.
- 61. (Original) The kit of claim 56 wherein said antibody fragment is conjugated to a cationic liposome.
- 62. (Canceled)
- 63. (Original) The kit of claim 56 wherein said cationic immunoliposome is in an aqueous solution.
- 64. (Original) The kit of claim 56 further comprising a nucleic acid for use as a positive control in a container separate from said cationic immunoliposome.

65. (Original) The kit of claim 64 wherein said nucleic acid encodes a reporter gene selected from the group consisting of luciferase,  $\beta$ -galactosidase and green fluorescent protein.
66. (Original) A method of transfecting cells with a desired nucleic acid wherein said method comprises administering the nucleic acid-cationic immunoliposome complex of the kit of claim 56 to said cells wherein said complex comprises said desired nucleic acid.
67. (Original) The method of claim 66 wherein said method is performed in vitro.
68. (Original) A method of transfecting cells in a tissue in an animal with a desired nucleic acid wherein said method comprises administering the nucleic acid-cationic immunoliposome complex of the kit of claim 56 to said cells wherein said complex comprises said desired nucleic acid.